

REMARKS

Claims 1-55 have been canceled, without prejudice.

Claims 56-91 are pending.

Claims 86-91 have been added. No new matter has been added.

The claims have been amended to indicate that the recited polypeptide or peptide comprises 5 or more contiguous amino acids. Support for the same may be found, for example, on page 2, last paragraph; page 3, second full paragraph; page 4, last paragraph and page 5, second full paragraph, of the specification.

For completeness, the applicants note that claim 56 has been amended to include further sequences of HCV type 3a and HCV type 5 which are further defined by new claims 86 and 91. Support for the 3a regions spanning 1556-1650 may be found, for example, at page 13 in the disclosure of the HCC153 sequence in the regions spanning 4664-4730 and shown in Figure 6.

SEQ ID NO:30, is mentioned on page 38 (4th bulleted point) of the description. The amino acid boundaries of SEQ ID NO:30 are described, for example, in Figure 7, where one of the other type 3a NS3/4 sequences, of isolate BR36, is indicated. The Sequence Listing discloses that SEQ ID NO:30 starts with DFWE.... and ends withACMS; the amino acid D (asp) at the first position corresponds to amino acid 1556 of the HCV polyprotein (see Figure 7), and, likewise the last amino acid S (ser) of SEQ ID NO:30 corresponds to amino acid 1650 of the HCV polyprotein (see Figure 7).

Claim 87, which refers to SEQ ID NOs:168 etc., are mentioned on page 39 (last bulleted point) of the description. SEQ ID NO:168 for instance has the sequence

TCGF.....HRMA, as described in the Sequence Listing. Figure 5 indicates that the first amino acid T (thr) corresponds to amino acid 127 of the HCV polyprotein. Likewise, the last amino acid A (ala) of SEQ ID NO:168 corresponds to amino acid 319 of the HCV polyprotein (see Figure 5). The HCV Core protein spans positions 1-191 of the HCV polyprotein, the HCV E1 protein spans positions 192-383 of the HCV polyprotein. As SEQ ID NO:168 (and all other sequences of claim 87) starts at position 127, it will be understood to contain part of the Core protein. Hence, these sequences are to be regarded as Core/E1 proteins, as claimed.

Claim 88, which refers to SEQ ID NO: 166, is described on page 39 (2nd last paragraph) of the description. SEQ ID NO:166 is one of the sequences aligned in Figure 5 and spans amino acids 1-126 of the HCV polyprotein (MSTN.....IDTL) in accordance with SEQ ID NO:166 in Sequence Listing. As the HCV Core protein spans positions 1-191 of the HCV polyprotein, SEQ ID NO:166 will be recognized by one of ordinary skill in the art as a Core protein.

Claim 89, which refers to SEQ ID NO:192, is described on page 40 (1st bulleted point) of the description. SEQ ID NO:192 has the sequence MSTN.....WAGW, as described in the Sequence Listing. As will be clear from the description above with regard to SEQ ID NO:166, "MSTN...." refers to the start of the HCV polyprotein Core. SEQ ID NO:192 can be allocated amino acids 1-96 of the HCV Core polyprotein based on the sequence alignments in Figure 5. SEQ ID NO:192 is moreover one of the sequences aligned in Figure 5.

Claim 90, which refers to SEQ ID NO:156, is described on page 40 (4th bulleted point) of the description. The specification further describes the sequence as a

Core/E1. SEQ ID NO:156 has the sequence TCGF.....HQMA. SEQ ID NO:156 will be recognized by one of ordinary skill in the art, in a manner similar to the description above with regard to SEQ ID NO:168, to spans amino acids 127-319 of the HCV polyprotein.

Claim 91, which refers to SEQ ID NOs:198 and 200, as described on page 40 (1st bulleted point) of the description, and SEQ ID NO:270, as described in the legend to Figure 7 (page 47). SEQ ID NOs:198 and 200 both cover the sequence CARTITT.....W(X/A)TY, as described in the Sequence Listing. SEQ ID NO:270 covers the sequence TITT.....WATY. SEQ ID NO:270 is one of the sequences aligned in Figure 7 (except for the first amino acid "T") and from Figure 7 one of ordinary skill in the art will appreciate that SEQ ID NO:270 spans amino acids 1284-1764 of the HCV polyprotein. SEQ ID NOs:198 and 200 both have 3 extra amino acids at their amino-terminus and thus span amino acids 1281-1764 of the HCV polyprotein. The common amino acids for the three SEQ ID NOs are 1284-1764, as recited in claim 91.

The claims have been amended to provide recite, in part, the subject matter of "Group" 2 of the International Search Report received in connection with the parent application PCT/EP94/01323. A copy of the relevant portion of the same is attached for the Examiner's convenience and consideration. That is, the claims of the present application are directed to "(polynucleotides or) amino acids corresponding to other regions of the genome of HCV subtypes 3, 3a and 3c and their uses" wherein "other regions" refers to regions "other than Core/E1", which is in "Group" 1 of the International Search Report (copy attached).

The applicants amendment of the claims in this regard, and the Examiner's examination of the same, would appear to be most appropriate as the Examiner has now required restriction in the Office Action of March 24, 2003, based on the principles of unity of invention, as described under PCT Rule 13.1 and "in accordance with 37 CFR 1.499". See, page 2 of the Office Action dated March 24, 2003 (Paper No. 22). Assuming the Examiner is following the principles of unity of invention, the Examiner should allow examination at least to the extent that the claims read on the subject matter of "Group" 2 of the International Search Report as the principles of unity of invention have been applied previously by the International Searching Authority and expressed in the attached portion of the International Search Report received in connection with the parent application PCT/EP94/01323.

For the Examiner's convenience, the applicants note that specific exemplified sequences defined by "Group" 2 of the attached International Search Report received in connection with PCT/EP94/01323, include the following:

SEQ ID NO:2 of region NS5B spanning 2675-2745;
SEQ ID NO:4 of region NS5B spanning 2675-2745;
SEQ ID NO:6 of region NS5B spanning 2675-2745;
SEQ ID NO:8 of region NS5B spanning 2675-2745;
SEQ ID NO:10 of region NS5B spanning 2675-2745;
SEQ ID NO:12 of region NS5B spanning 2675-2745;
SEQ ID NO:30 of region NS3/NS4 spanning 1556-1640;
SEQ ID NO:32 of region NS3/NS4 spanning 1632-1764;
SEQ ID NO:34 of region NS3/NS4 spanning 1632-1764;

SEQ ID NO:36 of region NS3/NS4 spanning 1632-1764;
SEQ ID NO:38 of region NS3/NS4 spanning 1632-1764;
SEQ ID NO:40 of region NS3/NS4 spanning 1632-1764;
SEQ ID NO:150 of region NS5B spanning 2661-2753;
SEQ ID NO:218 of region NS5B spanning 2645-2757; and
SEQ ID NO:223 of region NS3/NS4 spanning 1556-1764.

The nucleic acid sequences encoding the same are similarly disclosed.

The Examiner's restriction requirement is traversed. The basis for the restriction requirement is an allegation that the claims are drawn to "many thousands of polypeptides sequences and variations of polypeptides sequences and methods of using these sequences to prepare antibodies or in polypeptide binding assays." See, page 2 of Paper No. 22. The Examiner's unsupported asserted should not be sufficient to maintain a restriction requirement. The Examiner should, at a minimum, be required to support any restriction requirement pursuant to the requirements of the Rules and/or the MPEP.

The Examiner is further requested to appreciate that this application was filed August 15, 2000 and it has taken nearly three years to receive a restriction requirement relating to the subject matter of the present claims. Continued further restriction of the examined claims of this application and the requirement that further applications now be filed to pursue aspects of the presently claimed invention would be an undue burden on the applicants not only due to the delay in the Patent Office in examining the present application but also due to the fact that the applicants believe the subject matter of the

present claims has, in many respects, been previously examined and indicated as allowable over the art of record.

Specifically, the applicants note that the claims to nucleic acid sequences containing many of the corresponding protein sequences of the present application were indicated as allowed August 8, 2000 and May 7, 2001 in the parent application Serial No. 08/362,455. Specifically, the applicants believe that, with respect to the claims previously indicated as allowable in the parent application Serial No. 08/362,455, claim 56 of the present application would correspond in many respects to claim 24 of the allowed claims of the parent application; claim 58 of the present application would correspond in many respects to claim 41 allowed in the parent application; claim 86 would correspond in many respects to claim 43 allowed in the parent application; claim 59 of the present application would correspond in many respects to claim 44 allowed in the parent application; claims 64, 65 and 66 of the present application would correspond in many respects to claim 48 allowed in the parent application; claim 91 of the present application would correspond in many respects to claim 49 allowed in the parent application; claim 67 of the present application would correspond in many respects to claim 50 allowed in the parent application; claim 69 of the present application would correspond in many respects to claim 51 allowed in the parent application; claim 70 of the present application would correspond in many respects to claim 52 allowed in the parent application; claims 60, 61 and 87 of the present application would correspond in many respects to claims 54, 55, 56, 57, 58, 59, 60 and 61 allowed in the parent application; claim 62 of the present application would correspond in many respects to claims 62, 63, 64, 65, 66, 67 and 68 allowed in the parent application; claims 71 and 72

of the present application would correspond in many respects to claim 69 allowed in the parent application; and claim 73 of the present application would correspond in many respects to claim 70 in the parent application.

Beyond the correspondence of subject matter between the present application and allowed claims in the parent application 08/362,455, the applicants note that multiple sequences were examined and allowed in one application of the parent application Serial No. 08/362,455. As the Examiner has believed to have done a complete search, which was not an undue burden on the Examiner, in the parent application Serial No. 08/362,455, the applicants believe a search of more than a single sequence in the present application would not place an undue burden on the Examiner in this application.

In view of all the above, withdrawal of the restriction requirement of March 24, 2003, and an Action on the merits of all the pending claims is requested.

In the interest of being responsive only, and without prejudice to further petition to the Commissioner for withdrawal of any restriction requirement made final, the applications elect, with traverse, the single sequence of SEQ ID NO:36, which is currently specifically recited in claim 59.

The present paper is believed to be completely responsive to the Office Action of March 24, 2003, however the Examiner is requested to advise the undersigned if anything further is required.


An early and favorable action on the merits of all the claimed subject matter is requested.

MAERTENS et al.
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Respectfully submitted,

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